



Body Wise International, Inc.
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Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

RE: Notification of statements on a dietary supplement known as, AG-Immune®

July 22, 2003

Dear Ladies/Gentlemen;

Pursuant of 21 C.F.R. Subpart F, section 101.93, Body Wise International, Inc. ("Body Wise" the distributor, which is located at 2802 Dow Avenue, Tustin, CA 92780) wishes to notify the Food and Drug Administration that it has commenced marketing a dietary supplement known as AG-Immune® which includes statements of nutritional support in it's labeling.

The following statements are being made for the dietary supplement known as AG-Immune®:

- For support of a healthy immune system.
- We believe that AG-Immune® is the most powerful product created to support your immune-system health.
- AG-Immune® includes the immune system "trigger" antigen infused bovine colostrums/whey extract, Ai/E10®, along with herbal fuels that support immune system health.
- Arabinogalactan - supports macrophage activity.
- Arabinogalactan - supports gut immunity.
- Astragalus - supports healthy cytokine, interferon, interleukin, and natural killer cell levels.
- Maitake Mushroom D-fraction - supports healthy cytokine, interferon, interleukin, and natural killer cell levels.
- Maitake Mushroom D-fraction - maintains a healthy prostate gland.
- Maitake Mushroom D-fraction - supports blood pressure levels that are already within the normal range.
- Superior Immune System Support.

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- It also contains three nutritional fuels: maitake mushroom, arabinogalactan, and astragalus. These powerful ingredients help support healthy levels of important immune system components.
- It also contains three nutritional fuels: maitake mushroom, arabinogalactan, and astragalus. These powerful ingredients help support killer cell levels as well as other important immune system components.
- Arabinogalactan comes from the larch tree. It provides complex polysaccharides, which appear to support immune health in a few ways. It helps to support healthy gut immunity and healthy macrophage activity. Macrophages are powerful immune system components.
- Astragalus - Traditionally used in Chinese culture for the maintenance of healthy immune function. Preliminary research suggests that it helps to support immunological reactions such as maintaining healthy interleukin, interferon, and NK-cell levels, which are all very important to the immune system.
- Maitake Mushroom - This extract of the maitake mushroom may help maintain healthy cytokine, interferon, interleukin, and NK-cell levels. Preliminary research suggests that D-fraction has also been shown to maintain a healthy prostate gland and support blood pressure levels that are already within the normal range.
- We believe that AG-Immune® is the most powerful product created to support your immune-system health. It contains a proprietary form of an antigen infused bovine colostrums/whey extract (Ai/E10®). It also contains three nutritional fuels; Maitake mushroom, arabinogalactan, and astragalus. These powerful ingredients help support healthy natural killer cell levels as well as other important immune system components.

The above statements are accompanied by the required disclaimer, which is prominently displayed in a box in boldfaced type.

The information contained in this notice is complete and accurate. Body Wise maintains on file substantiation that these statements are truthful and non-misleading.

An original and two copies of this notification are being submitted.

Sincerely,



Alan E. Huffington
Director of Regulatory Affairs

dw/AEH

Enclosures